



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450  
www.uspto.gov

JIGlr: 03-06

Paper No: 11

WENDY M LEE  
GENENTECH INC  
1 DNA WAY  
SOUTH SAN FRANCISCO CA 94080-4990

**COPY MAILED**

**JUN 22 2006**

**OFFICE OF PETITIONS**

In re Application of

Fendly

Application No. 09/705,579

Filing Date: 2 November, 2000

Attorney Docket No.: P1053R1D1

:

:

:

ON PETITION

This is a decision on the petition of 19 April, 2006, under 37 C.F.R. §1.182 to withdraw the terminal disclaimer filed of record in the instant application on 16 March, 2004.

The petition under 37 C.F.R. §1.182 to withdraw the terminal disclaimer is **DISMISSED**.

**BACKGROUND**

Petitioner avers that:

- in response to the requirement of the Examiner for a disclaimer to overcome a double-patenting rejection as to the instant application, Petitioner filed on 16 March, 2004.
- the terminal disclaimer (TD) was accepted as submitted;
- thereafter, Petitioner proceeded through prosecution and now avers that “a TD over US Patent No. 5,720,954 \* \* \* is not required in view of the evidence of unexpected results[,]” and Petitioner seeks to withdraw the terminal disclaimer;
- it is noted that Petitioner continues in prosecution of the application, and in so doing filed a request for continued examination (RCE) with fee and submission under 37 C.F.R. §1.114

contemporaneously with the instant petition;

- further, the Examiner has, as of this writing, refused to agree to the withdrawal.

### LAW AND ANALYSIS

Congress has provided at 35 U.S.C. §253:

A patentee, whether of the whole or any sectional interest therein, may, on payment of the fee required by law, make disclaimer of any complete claim, stating therein the extent of his interest in such patent. Such disclaimer shall be in writing, and recorded in the Patent and Trademark Office; and it shall thereafter be considered as part of the original patent to the extent of the interest possessed by the disclaimant and by those claiming under him. In like manner any patentee or applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted.

The regulations at 37 C.F.R. §1.183 provide that:

In an extraordinary situation, when justice requires, any requirement of the regulations in this part which is not a requirement of the statutes may be suspended or waived by the Director or the Director's designee, *sua sponte*, or on petition of the interested party, subject to such other requirements as may be imposed. Any petition under this section must be accompanied by the petition fee set forth in §1.17(h).

The regulations at 37 C.F.R. §1.321 provide in pertinent part:

\* \* \*

(b) An applicant or assignee may disclaim or dedicate to the public the entire term, or any terminal part of the term, of a patent to be granted. Such terminal disclaimer is binding upon the grantee and its successors or assigns. The terminal disclaimer, to be recorded in the Patent and Trademark Office, must:

(1) be signed:

(I) by the applicant, or

(ii) if there is an assignee of record of an undivided part interest, by the applicant and such assignee, or

(iii) if there is an assignee of record of the entire interest, by such assignee, or

- (iv) by an attorney or agent of record;
  - (2) specify the portion of the term of the patent being disclaimed;
  - (3) state the present extent of applicant's or assignee's ownership interest in the patent to be granted; and
  - (4) be accompanied by the fee set forth in § 1.20(d).
- (c) A terminal disclaimer, when filed to obviate a judicially created double patenting rejection in a patent application or in a reexamination proceeding, must:
- (1) Comply with the provisions of paragraphs (b)(2) through (b)(4) of this section;
  - (2) Be signed in accordance with paragraph (b)(1) of this section if filed in a patent application or in accordance with paragraph (a)(1) of this section if filed in a reexamination proceeding; and
  - (3) Include a provision that any patent granted on that application or any patent subject to the reexamination proceeding shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the rejection.

\* \* \*

Citing to a 9 February, 2006, Advisory Action, Petitioner states “[t]he Patent Office has indicated that the evidence [submitted by Petitioner in an after-final amendment filed on 16 December, 2005] does ‘indicate synergistic effects if the anti-HER2 antibody in combination with vinorelbine for the treatment of breast cancer.’”

Petitioner may find that taking pieces of sentences out of context can have erroneous, misleading and deceptive results.

Petitioner failed to note—and to include in her presentation—the sentences that precede and follow the clipped passage from the 9 February, 2006, Advisory Action , which states:

\* \* \*

[Petitioner’s references] are not commensurate in scope to what is being claimed. The references relied upon indicate [synergistic] effects of the anti-HER2 antibody in combination with vinorelbine for the treatment of breast cancer. The claims of the instant invention are drawn to the treatment of a broad array of cancer or tumors (i.e., those that overexpress or have activated ErbB2). Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the “objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is

offered to support.” In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range (Citations omitted.) (Continuation Sheet, Page 2)

\* \* \*

Petitioner apparently misreads—and so misinterprets—the Examiner’s words.

Out of an abundance of caution, Petitioners always are reminded that those registered to practice *and* all others who make representations before the Office are reminded to inquire into the underlying facts of representations made to the Office and support averments with the appropriate documentation—since all owe to the Office the continuing duty to disclose.<sup>1</sup>

---

<sup>1</sup> See supplement of 17 June, 1999. The Patent and Trademark Office is relying on petitioner’s duty of candor and good faith and accepting a statement made by Petitioner. See Changes to Patent Practice and Procedure, 62 Fed. Reg. at 53160 and 53178, 1203 Off. Gaz. Pat. Office at 88 and 103 (responses to comments 64 and 109)(applicant obligated under 37 C.F.R. §10.18 to inquire into the underlying facts and circumstances when providing statements to the Patent and Trademark Office).

Specifically, the regulations at 37 C.F.R. §10.18 provide:

**§ 10.18 Signature and certificate for correspondence filed in the Patent and Trademark Office.**

(a) For all documents filed in the Office in patent, trademark, and other non-patent matters, except for correspondence that is required to be signed by the applicant or party, each piece of correspondence filed by a practitioner in the Patent and Trademark Office must bear a signature by such practitioner complying with the provisions of §1.4(d), §1.4(e), or § 2.193(c)(1) of this chapter.

(b) By presenting to the Office (whether by signing, filing, submitting, or later advocating) any paper, the party presenting such paper, whether a practitioner or non-practitioner, is certifying that—

(1) All statements made therein of the party’s own knowledge are true, all statements made therein on information and belief are believed to be true, and all statements made therein are made with the knowledge that whoever, in any matter within the jurisdiction of the Patent and Trademark Office, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be subject to the penalties set forth under 18 U.S.C. 1001, and that violations of this paragraph may jeopardize the validity of the application or document, or the validity or enforceability of any patent, trademark registration, or certificate resulting therefrom; and

(2) To the best of the party’s knowledge, information and belief, formed after an inquiry reasonable under the circumstances, that —

(i) The paper is not being presented for any improper purpose, such as to harass someone or to cause unnecessary delay or needless increase in the cost of prosecution before the Office;

(ii) The claims and other legal contentions therein are warranted by existing law or by a nonfrivolous argument for the extension, modification, or reversal of existing law or the establishment of new law;

(iii) The allegations and other factual contentions have evidentiary support or, if specifically so identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery; and

(iv) The denials of factual contentions are warranted on the evidence, or if specifically so identified, are reasonably based on a lack of information or belief.

(c) Violations of paragraph (b)(1) of this section by a practitioner or non-practitioner may jeopardize the validity of the application or document, or the validity or enforceability of any patent, trademark registration, or certificate resulting therefrom. Violations of any of paragraphs (b)(2)(i) through (iv) of this section are, after notice and reasonable opportunity to respond, subject to such sanctions as deemed appropriate by the Commissioner, or the Commissioner’s designee, which may include, but are not limited to, any combination of —

(1) Holding certain facts to have been established;

(2) Returning papers;

(3) Precluding a party from filing a paper, or presenting or contesting an issue;

(4) Imposing a monetary sanction;

(5) Requiring a terminal disclaimer for the period of the delay; or

(6) Terminating the proceedings in the Patent and Trademark Office.

(d) Any practitioner violating the provisions of this section may also be subject to disciplinary action. See § 10.23(c)(15).

[Added 50 FR 5175, Feb. 6, 1985, effective Mar. 8, 1985; para. (a) revised, 58 FR 54494, Oct. 22, 1993, effective Nov. 22, 1993; paras. (a) & (b) revised, paras. (c) & (d) added, 62 FR 53131, Oct. 10, 1997, effective Dec. 1, 1997; para. (a) revised, 69 FR 56481, Sept. 21, 2004, effective Oct. 21, 2004]

The Patent and Trademark Office must rely on the actions or inactions of duly authorized and voluntarily chosen representatives of the applicant, and applicant is bound by the consequences of those actions or inactions.<sup>2</sup>

**The instant file is being released to the Examiner in Technology Center 1600 for further processing in due course.**

Telephone inquiries regarding this decision should be directed to the undersigned at (571) 272-3214.

A handwritten signature in black ink, appearing to read 'J. Gillon, Jr.', with a stylized flourish at the end.

John J. Gillon, Jr.  
Senior Attorney  
Office of Petitions

---

<sup>2</sup> Link v. Wabash, 370 U.S. 626, 633-34 (1962); Huston v. Ladner, 973 F.2d 1564, 1567, 23 USPQ2d 1910, 1913 (Fed. Cir. 1992); see also Haines v. Quigg, 673 F. Supp. 314, 317, 5 USPQ2d 1130, 1132 (D.N. Ind. 1987).